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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09,648,864	08/25/2000	Howard M Johnson	UF-243X	6790

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,864

Applicant(s)

JOHNSON ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 24 February 2003 is acknowledged. Claims 25 and 30-39 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Maintained

2. The rejection of claims 25 and 30-39 is maintained for reasons of record in the office actions of paper nos. 10 and 14.

Applicant has provided arguments and a declaration under 37 C.F.R. 1.132 indicating that one of ordinary skill in the art would not expect IFN- γ to have the same effects on IgE production as IFN- α . Applicant argues that there is uncertainty as to the functional activities of the type I interferons, and states that there are differences even among the different IFN- α s. Applicant argues that it is not known exactly what genes are activated by IFN- α and IFN- γ and that the references cited by the Examiner do not provide an expectation of success.

The declaration under 37 C.F.R. 1.132 states that there are more than 15 different IFN- α proteins and that they vary in specific activity, and further that these differences were determined empirically. The declaration further states that there is little knowledge of the pattern of gene activation by the various type I interferons, citing Brierly et al. The declaration, citing Kotenko et al., also states that there may be previously unknown receptor subunits, and that the relationship of IFN- γ to these subunits is not known. The declaration further states that there are no reports indicating that IFN- γ activates the same transcription factors as IFN- α . Citing Ramana et al., the declaration indicates that IFNs may have effects independent of STATs and notes that the EGF receptor directly activates genes in the nucleus. The declaration concludes that, based

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on the art, one of ordinary skill would as readily predict that IFN- τ would not downregulate IgE production.

Applicant's arguments and declaration have been fully considered but have not been found to be persuasive. That there are differences in specific activity and toxicity among the various IFN- α s would not indicate to one of ordinary skill in the art that they have different functions. Since they are known to act through the Type I receptor, one of ordinary skill in the biochemical arts would conclude that they have the same biochemical effects and merely vary in their relative ability to induce these effects. Rogge et al., cited by Applicant, teach that IFN- α and IFN- β , which are type I interferons, have the same effects (p. 6572, for example) and in fact refers to these two interferons throughout as "IFN- α/β ", distinguishing them not from each other but from the type II interferon, IFN- γ . Fasler-Kan et al. similarly contrasts IFN- α with IFN- γ (p. 578); that neither of these teachings addresses IFN- τ does not indicate that it would behave any differently from other type I IFNs. The teachings of Barnes et al., also cited by Applicant, provide no teachings to indicate that there is any qualitative difference in the effects of the different type I IFNs; the teachings are directed to differences in regulation of the expression of the various IFNs, not to differences in their effects. Brierly et al. teaches that all type I interferons activate the same receptor. There is no teaching that the different type I IFNs activate different pathways, only that activation of the pathway results in many subsequent events. Brierly concludes on p. 840 that the IFN- α s and IFN- β , which are, like IFN- τ , type I IFNs, elicit similar biological activities and differ only in their specific activity, resulting in different doses being required to achieve the same effect, not in qualitatively different effects. Kotenko et al. also fails to teach that IFN- α and IFN- τ have different effects. This reference teaches a ligand-

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receptor system that is different from that identified for the type I interferons but at no point even suggests that there are any qualitative differences in the effects of type I interferons. The new IFN identified, IFN- λ , is shown in Figure 3, p. 72, to be distinct from type I interferons and is explicitly taught in the abstract to be distinct from them.

Ramana et al. and Lin et al. teach, respectively, that IFN- γ , which is not a type I IFN, has effects not mediated through STATs and that the EGF receptor is capable of directly activating genes via nuclear translocation. That cytokines may act through mechanisms that were not previously understood does not indicate why one of ordinary skill would believe that cytokines known to act in the same way would have different effects, regardless of how those effects are mediated.

What was stated in the office actions of paper nos. 10 and 14 was that IFN- τ is a type I IFN and thus would be expected by one of ordinary skill in the art to behave like another type I IFN, IFN- α . That there is more than one IFN- α , or that different doses of the different type I IFNs are required to achieve the same effect, that type I IFNs have many different effects, or that proteins may exert mediate their effects in different ways does not serve to indicate to one of ordinary skill in the art that any type I IFN would have not have the same effects that other type I IFNs have. Thus Applicant's arguments and declaration do not indicate why it would not be *prima facie* obvious to one of ordinary skill in the art, knowing that IFN- α downregulated IgE production, to use another IFN of the same type, known to function in the same way, for the same purpose.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly

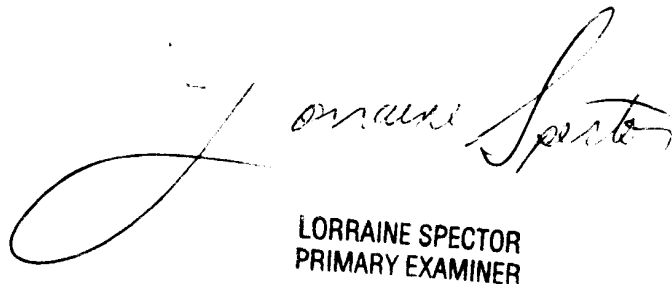
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signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

May 8, 2003



LORRAINE SPECTOR
PRIMARY EXAMINER